ENHANCING SCIENTIFIC COLLABORATION THROUGH QUALITY ASSURANCE

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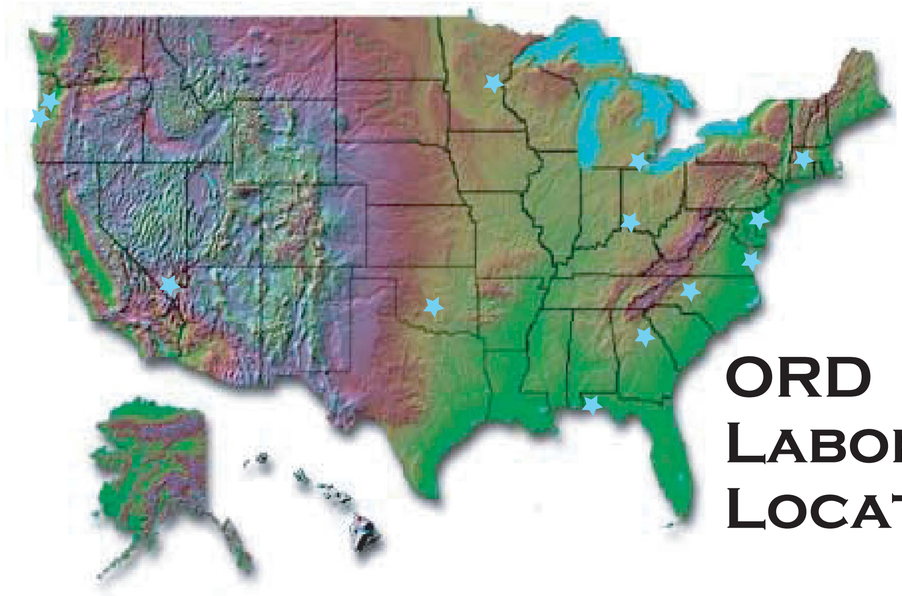
Background

EPA Administrator Douglas Costle in 1979 states "*The EPA must have a comprehensive quality assurance effort to provide for the generation, storage, and use of environmental data which are of known quality*."

- Since then, EPA has developed policies, specifications, and guidance for implementing a mandatory, Agency-wide quality assurance (QA) program.
- Leadership for the QA program currently resides in EPA's Office of Environmental Information.
- Implementation of the QA program is the responsibility of approximately 30 different EPA organizations.
- The Office of Research and Development (ORD) is composed of a number of offices/centers/laboratories. Each of the three National Laboratories has a quality management plan that describes a quality system that meets both the needs of their organization and the specifications of the Agency-wide QA program.

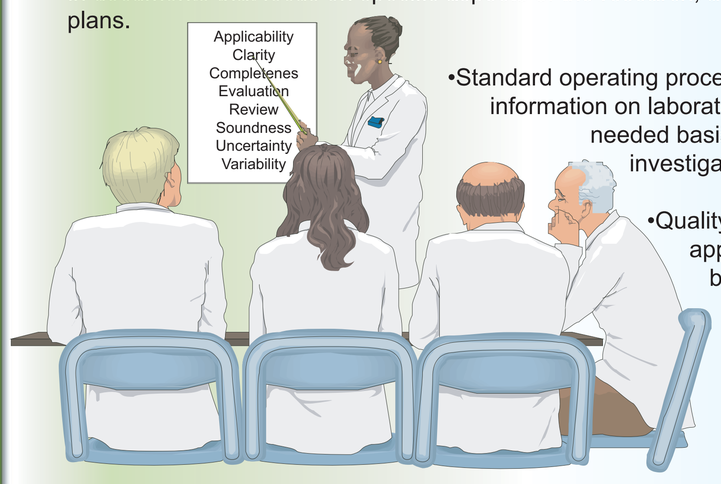


ORD Laboratory Locations

Collaboration and QA

Collaborators benefit from a clear and common understanding of research goals, methods, and analytic approaches. The ORD QA program can facilitate these communications by offering a structured and proven approach to research planning and implementation.

- For large programs with multiple external collaborators, like the Environmental Technology Verification program, a quality system specific to the program is described in an overarching document, typically called a quality management plan.
- For individual research projects, issues related to project management and quality control are described in documents that focus on specific aspects of the research, and are typically referred to as QA project plans.



- Standard operating procedures contain the most detailed information on laboratory procedures and are prepared on an as needed basis, as determined by the principal investigators.
- Quality documents are routed for review and approval by project and QA professionals both within ORD and within the collaborators organization.
- The preparation of QA documentation, whether it is a quality management plan, QA project plan, and/or standard operating procedures insures that ORD researchers and their collaborators agree to specific scientific checks and balances that lead to positive research outcomes.

EPA Information Quality Guidelines

EPA is one of many Federal agencies that developed policy and procedural guidance to comply with congressional and OMB requirements for ensuring and maximizing the quality of information disseminated by the Agency.

- The guidelines recognize that some information is more "influential" than other information and will require a higher degree of quality, which includes a higher degree of transparency and reproducibility.
- The guidelines rely on commonly accepted scientific practice for insuring reproducibility, but acknowledge more specific guidance can only be obtained through consultation with the scientific community.
- ORD has implemented policies and procedures dealing with planning documentation, record-keeping, and assessments that acknowledge the need for differing levels of transparency and reproducibility for research conducted by or for ORD.
- Information disseminated by EPA collaborators is covered by the guidelines only when collaborators are specifically directed to disseminate information on EPA's behalf.
- EPA created the document *A Summary of General Technical Factors for Evaluating the Quality of Scientific and Technical Information* that EPA will use to evaluate information that comes from both within and outside the Agency. Information is generally acquired by EPA as the result of in-house research, a contract or grant, or through compliance reporting, or it is voluntarily submitted..

Help Us With Laboratory Competency

The Agency Science Advisor issued a new policy directive in 2004 calling for "periodic independent assessments" of each laboratory's adherence to their documented quality system.

- ORD is complying with this policy using laboratory accreditation programs, whenever possible.
- Most ORD laboratory science is not amenable to laboratory accreditation programs.
- ORD laboratories are looking to Federal research scientists from outside of EPA to help us conduct these independent assessments.
- ORD will use invitational travel to assist Federal researchers willing to travel to ORD laboratories to participate in assessments.

CALL FOR FEDERAL RESEARCH SCIENTISTS
TO PARTICIPATE IN OUR EXTERNAL ASSESSMENT PROGRAM

NAME:

AREA OF EXPERTISE:

ADDRESS:

PHONE NUMBER: E-MAIL:

BEST TIME OF YEAR AVAILABLE:

INTERESTED IN A RECIPROCAL ARRANGMENT? Y N

HAVE YOU EVER BEEN ON AN AUDIT TEAM? Y N

DO YOU KNOW ANYONE ELSE THAT WOULD BE INTERESTED, IF SO PLEASE NAME.

Scientific Ethics

Retaining public confidence in science relies on the ethical behavior of the scientific community. This is particularly true for researchers who benefit from federal funding of their work.

- Federal policy on research misconduct was published in the Federal Register in 2000 by the Office of Science and Technology Policy
- Research misconduct is defined as fabrication, falsification, and plagiarism and covers both federal employees and employees of research institutions that receive federal funds.
- The policy recognizes the research process is a shared responsibility between the funding agency and the research institution.
- Research institutions are identified as having primary responsibility for preventing, detecting, and investigating research misconduct.
- ORD has begun training in scientific ethics under the umbrella of the QA program and has relied on two publications: *The Responsible Researcher: Paths and Pitfalls*, Sigma XI, 1999 and *Honor in Science*, Sigma XI, 2000

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